INSTRUCTIONS FOR USE
IMPLANTS

MANUFACTURER IDENTIFICATION
The Manufacturer and Person responsible for placing on the market in the EU the Medical Devices called Dental Implants covered by this Instructions for Use is:

Errecieffe S.r.l.
Via V. Emanuele II, 68 - 24036 PONTE SAN PIETRO (BG) ITALY
Tel. +39 340 5181203 www.errecieffe.com info@errecieffe.com

DEVICE IDENTIFICATION
Dental implants of the ERRECIEFFE line with related surgical screws (where provided) and related implantable prosthetic components.

Intended use:
Dental implants (implant fixtures) are implantable devices (metal elements) designed to rehabilitate patients suffering from partial or total edentulism for the restoration of masticatory, phonetic or aesthetic function. They are intended to be surgically inserted into the mandibular or maxillary bone.

MATERIALS
The devices are made in:
Titanium grade4.
Titanium Grade5.

How to use / Indications
Dental implants can be inserted in different locations in the oral cavity with various techniques and then connected to the prostheses with different timing. Depending on the surgical protocol, they can be implanted with or without a submerged protocol; based on the timing of use (functionalization) they can be rehabilitated with immediate, anticipated or deferred loading.
They can be inserted in edentulous sites or in post-extraction sites, both with immediate loading (insertion of the implant at the same time as the removal of the tooth or root), and deferred (a period of about 3 weeks is normally left between extraction and insertion of the implant fixture.

DM Description
The ERRECIEFFE implant line is the alternative to implants already on the market, being "compatible" with others already on the market. The surgical procedures and warnings are the same as that normally used by the doctor.

Errecieffe has developed a surgical sequence for the insertion of the implants. This document, which specifies the type of drills to be used for site preparation, can be requested or downloaded from our website in the documents section.

OnlyOne implants have the multi-unit (MUA) abutment (straight or angled) incorporated in the implant. They have the same characteristics of the usual implants, even during prosthesis phase. The only difference is the use of a particular mounter with a special coupling for their insertion into the bone. The advantage is that the multi-unit abutment is already positioned on the implant, avoiding the difficult assembly during successive steps. These implants are an evolution of the "on all four" technique and they are used for fixed prostheses with immediate loading. The OnlyOne version (one piece) allows for better stability; since there is no connection, therefore not even movement and unscrewing. Only One implants have a greater strength and a statistically high implant/prosthetic survival, as demonstrated in the literature. It is necessary to use at least four implants, as required by the technique. The mini monophasic implants (with fixed or ball abutment) can be employed, with the immediate loading technique, for the stabilization of removable dentures, with thin crests or even for the replacement of individual teeth. Mini implants with ball abutment allow the application of nylon retentive attachments.

EXTERNAL HEXAGON IMPLANTS

Code	Diameter mm	Platform Ø mm	Hexagon of connection	Tightening screw thread
EH SP implant	3,3	3,5	2,4	M 1.60
EH MP implant	3,7	4,1	2,7	M 2.00
EH MP implant	4,0	4,1	2,7	M 2.00
EH LP implant	5,0	5,1	3,4	M 2.50

INTERNAL HEXAGON IMPLANTS (TYPE A)

Code	Diameter mm	Platform Ø mm	Hexagon of connection	Tightening screw thread
IH SP implant	3,3	3,5	2,4	M 1.80
IH MP implant	3,7	4,0	2,4	M 1.80
IH MP implant	4,2	4,0	2,4	M 1.80
IH MP implant	5,0	4,0	2,4	M 1.80
IH LP implant	5,0	5,0	2,4	M 1.80

INTERNAL HEXAGON IMPLANTS (TYPE Z)

Code	Diameter mm	Platform Ø mm	Hexagon of connection	Tightening screw thread
IH MP implant	3,3	3,5	2,4	M 1/72
IH MP implant	3,7	3,5	2,4	M 1/72
IH MP implant	4,2	3,5	2,4	M 1/72
IH MP implant	5,0	3,5	2,4	M 1/72

INTERNAL CONICAL CONNECTION IMPLANTS

Code	Diameter mm	Platform	Hexagon of connection	Tightening screw thread
IH SP implant	3,3	Narrow	2,2	M 1.60
IH SP implant	3,7		2,2	M 1.60
IH MP implant	4,2	Regular	2,6	M 2.00
IH MP implant	5,0		2,6	M 2.00
IH MP implant	5,5		2,6	M 2.00

Monophasic dental implants	Diameter	Length
monophasic implants with MUA incorporated (OnlyOne)	3.30 - 4.00 mm	10 - 18 mm
Monophasic mini-implants	2.70 - 3.20 mm	8.5 - 15 mm

CONTRAINDICATIONS

In evaluating the patient, in addition to considering the suitability for an implant-prosthetic rehabilitation, it is generally necessary to take into account the contraindications valid for dental surgery.

Absolute contraindications

The insertion of implants and implantable prostheses is contraindicated in patients with poor general health, poor or insufficient oral hygiene, impossibility or limited possibility of controlling their general conditions, or who have previously undergone organ transplants. Patients who are mentally ill, or who abuse alcohol, tobacco or drugs, who have serious neurological diseases, severe impairment of the immune system, chemotherapy in progress must also be discarded.

In the case of administration of bisphosphonates, numerous cases of peri-implant bone necrosis have been reported in the literature, mainly in the mandible. This problem particularly affects patients undergoing intravenous treatment.

Related contraindications
Patients with poor periodontal status must be previously treated and recovered or in the presence of infections and inflammations such as: periodontitis, gingivitis. In the event of a lack of bone substance or poor quality of the recipient bone, such that the stability of the implant may be compromised, an appropriate guided tissue regeneration must be carried out beforehand. Metabolic or systemic diseases that compromise tissue regeneration. Intolerances or allergies to the material constituting the devices in question, dialysis, osteoporosis.

WARNINGS
The risks of implant surgery include: perforation of the labial or lingual plate, bone fractures, implant fractures, fractures of the superstructures, cosmetic problems, inadvertent perforation of the nasal sinus, nerve injuries, compression of the natural dentition. The following pathophysiological problems may increase the risks: cardiovascular failure, chronic disorders, arrhythmia, chronic lung or respiratory diseases, gastrointestinal diseases, hepatitis, intestinal inflammation, chronic kidney failure, urinary system disorders, endocrine disorders, diabetes, thyroid disease, hematologic problems, anemia, leukemia, coagulation problems, osteoporosis or musculoskeletal arthritis, heart attack, neurological disorders, delays paralysis.

In case of damaged packaging, damaged or non-compliant device, do not use the device and notify the manufacturer or distributor about the problem.
Maximum importance must be given by users to cleaning, disinfection and sterilization of the environment in which the intervention is performed and of the equipment used to avoid the onset of infections or the occurrence of cross-infections.
The devices in question are made of Titanium grade 4 for biphasic dental implants and grade 5 for monophasic mini implants. Titanium is a non-ferromagnetic material that does not interact with the presence of magnetic fields. In the case of diagnostic investigations (e.g. MRIs) it is however recommended to notify the staff before carrying out the examination of the presence of devices implanted in Titanium. Do not use the devices in question on patients with titanium intolerance or allergy.
Users must carry out the surgery wearing all the protective devices required for their profession correctly (e.g. mask, gowns, gloves, goggles) and pay the utmost attention to avoid minor injuries from contact with devices with sharp or pointed portions and to avoid contaminating themselves with the patient's saliva or blood and to avoid contaminating the patient in turn.

The dental implants in question are disposable devices supplied sterile. No reconditioning by the user is permitted. Once the sterile packaging has been opened, the implant must be used immediately, otherwise it must be thrown away.
Pay attention to the expiration date on the label of each package. Expired implants should not be used as sterility is not guaranteed.
No re-sterilization process is allowed by the user. Sterilization not carried out by the manufacturer does not guarantee the sterility of the device.

SIDE SYMPTOMS
As a precautionary measure, the patient should avoid activities that require physical exertion after surgery.
Among the manifestations that accompany surgery, temporary complications such as pain, swelling, pronunciation problems, gingivitis, temporary local swelling, edema, hematomas, temporary limitations of sensitivity, temporary limitations of masticatory functions, post-operative micro-hemorrhages in the following 12/24 hours may occur. After dental implant operations, the following may occur: loss of bone crest, permanent paresthesia, dysesthesia, local or systemic infections, exfoliation, hyperplasia, oroantral and oronasal fistulas.

PREPARATORY TREATMENT INFORMATION
Pre-operative planning and preparation.
The preparation phase for the intervention includes:
general medical and dental history, general medical examination, clinical (complete haematogram) and radiological examinations, CT scan and consultation with the family doctor;

information to the patient (indications, contraindications, clinical picture, expectations, normal success and failure rates, need for periodic post-checks; hygiene plan, with possible periodontal interventions);
adoption of the necessary pharmacological prescriptions;
pre-prosthetic surgical planning in collaboration with the dental technician;
risk assessment of inadequate soft and hard tissue treatment;
prosthetic planning in collaboration with the dental technician.

SURGICAL INTERVENTION
Surgical techniques for implants are taught in universities to dental graduates.
However, the following factors should be taken into account:
tissues, both hard and soft, must be treated with extreme care, taking all the necessary precautions to obtain a good integration of the implant;
the normal biological principles of osseo-integration must be respected;
thermal trauma must be avoided as they would necrotize and compromise the possibility of osseo-integration. For this purpose, adequate drilling speeds must be used, drills with a cutting edge in excellent condition, drilling must be carried out intermittently, cooling the site with the necessary irrigation and the hole must be enlarged using drills with progressively larger specific diameters;
It is essential to respect the healing times recommended in implant surgery and to periodically check, even with X-ray checks, the progressive state of bone integration.

DEVICE ACCESSORIES

Description of other devices used in conjunction with the device

Surgical screw (or screw cap)	It can be used in the post-operative phase and whose duration of use can normally be used for a continuous duration of more than 30 days. It is the Clinician's faculty to use it in the post-operative phase.
Mounter	Used only as a transport device for inserting the fixture into the oral cavity, the duration of which can normally be used for a continuous duration of less than 60 minutes.

Additional devices, which can be used with dental implants (covered in the relevant Technical Files), are:

Healing (or transmucosal) abutments	Small direct-screwing abutments, of different heights according to the different implant systems, intended to recondition the emergence profiles of the mucous membranes, before prosthetic loading. They are surgical invasive devices intended for the oral cavity, for long term.
Temporary abutments	Temporary abutments, normally composed of a titanium base with an upper cannula on which the dentist or dental technician re-bases an acrylic-type prosthesis. In some versions they are made in Peek, which can be modified by milling from the laboratory or by the doctor directly to the chair. Peek is not resin-based, so these abutments are normally used for the rehabilitation of single prostheses by cementing a crown.

Abutments for traditional screw-retained prostheses	Straight and angled abutments for cemented prostheses. Millable abutments, preformed for cemented prostheses. They are customized by milling by the dental laboratory or by CAD-CAM techniques by milling centers. Castable pillars with preformed alloy base. They are used to obtain individual abutments for cemented prostheses or for overdenture bars or structures for screw-retained bridges such as Toronto Bridge by overcasting in the dental laboratory. Titanium bases equipped with connection to the implant, which in the upper part have a standard coupling cone for CAD-CAM techniques. Abutments that are preferably used for screwing multiple prostheses (Toronto-type prostheses) of the traditional type (straight with direct screwing) and for the MUA technique (for the correction of large disparellelisms, complete with the relative screws for fixing them on the implants).
Removable Overdenture Attachment Components	Spherical attachments that function as buttons for the stabilization of a total prosthesis. Spherical attachments require that a suitable matrix is positioned inside the prosthesis in correspondence with the attachments capable of hooking onto the spherical heads of the attachments themselves. These males are made up of caps in polyamide, or in gold alloy, or in titanium or by O-Ring type attachments.
Transfer	They have the function of transferring the exact position of the implant connection from the mouth to the dental model, in terms of height, inclination and indexing. There are various types of transfers: tear-off, pick-up technique transfer and (limited to some implantological systems) pull-up type. Special transfers (CAD-CAM transfers) are also available, intended to be screwed onto the plaster models and not in the mouth, which allow the use of three-dimensional software to transfer the position of the platforms from the plaster models to virtual CAD models for the subsequent techniques for making individual prostheses using the CAM process.
Castable abutments	They are used to obtain, by casting in the dental laboratory, individual pillars for cemented prostheses or for the fusion of bars for overdentures or structures for screw-retained bridges such as Toronto Bridge.
Tightening screws for abutments and Superstructures	These are the screws needed to screw pillars and superstructures.

USERS
The use and handling of the medical device is reserved for medical and dental personnel with the necessary professional qualification and training.

THE CHOICE OF THE DEVICE MUST BE CONSEQUENT TO AN ACCURATE PATIENT HISTORY
Specific responsibilities
Errecieffe products for oral implantology meet the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS established by Regulation (EU) 2017/745-MDR. Any use of the products other than the specific one is to be considered as "improper use", relieving the manufacturer of any liability.

DISPOSAL PROCEDURES
The components, if removed from the oral cavity due to biological or mechanical failure, must be assimilated to biological waste, according to the regulations in force at local level.

INCIDENT REPORTING
In accordance with SECTION 2 VIGILANCE, Article 87 Reporting of serious incidents and safety corrective actions of MDR 745/2017/EU, DL 15 November 2005 and MEDDEV guideline 2.12-1, it is recalled that public or private healthcare professionals are required to report accidents or near misses with Medical Devices to the manufacturer (Errecieffe S.r.l.) or to the National Competent Authorities as a matter of urgency.
An accident is defined as any dysfunction or deterioration in the characteristics and/or performance of a device, as well as any deficiency in labelling or instructions for use which, directly or indirectly, may cause or have caused death or a serious deterioration in the state of health of the patient or a user or other persons.

IMPLANT PASSPORT
Errecieffe S.r.l. provides, together with the Medical Device, the card for the dental implant with the related information that is provided to the patients.

SUMMARY DOCUMENT ON SAFETY AND CLINICAL PERFORMANCE
See SUMMARY document at EUDAMED website

FURTHER INFORMATION
This device does not contain software.
This device must be sterilized before use (the device is supplied in NON-STERILE condition).
This device is intended for re-use.
This device is not intended for use by lay users.
The device is not listed as a product that does not have a medical use.

LIABILITY FOR DEFECTIVE PRODUCT AND WARRANTY TERMS
Optimal patient care and attention to his needs are necessary conditions for implantological success and it is therefore necessary to carefully select the patient, inform him of the inherent risks and duties associated with the treatment and encourage him to cooperate with the dentist for the success of the treatment itself.
It is therefore necessary that the patient maintains good hygiene, confirmed during check-ups and follow-up appointments; it must always be ensured and documented as, moreover, the indications and prescriptions of the doctor before and after surgery must be observed and documented.
The instructions provided by Errecieffe S.r.l. are available at the time of treatment and accepted by dental practice; they must be observed and applied at all stages of care: from the patient's medical history to post-operative check-ups.
The warranty covers only ascertained production defects, upon shipment of the part identified by article number and batch, within the warranty period. The warranty clauses are available on the www.errecieffe.com website.

LEGEND OF SYMBOLS USED ON PACKAGING

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Manufacturer's Name		CE marking with identification of the Notified Body
	Sterile by irradiation		Non-sterilizable product
	Single-use product, do not reuse		Do not use if the packaging is damaged
	Consult the instructions for use		Caution! See instruction for use
REF	Device ID - Code	LOT	Batch number
UDI	Unique Device Identification - Alphanumeric code that uniquely identifies a medical device	MD	The product is a Medical Device
	Expiration Date		Distributor

DATE AND VALIDITY OF THESE OPERATING INSTRUCTIONS
These operating instructions are valid and effective from July 2024.